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Research Article

Development and Validation of New Stability Indicating HPLC Method for the Quantitative Determination of Topiroxostat in Bulk and Dosage Form

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ABSTRACT

Topiroxostat is a novel xanthine oxidoreductase (XOR) inhibitor; used to treat hyperuricemia and gout. The system comprised; column of Agilent Zorbax Bonus RP C18 (250×4.6) mm, 5 µ and mobile phase containing 50 milli molar potassium dihydrogen phosphate, which had a pH of 3.3 (adjusted by 5% OPA) and ACN, in 20:80, v/v ratio. The mobile phase was pumped through the column at a temperature of 30°C and a flow rate kept at 1-mL/min. Topiroxostat had retention time of 6.99 minutes, at 272 nm. According to the ICH guidelines, the developed approach has undergone statistical validation. The calibration curve was linear from 0.01 to 120 µg/mL with excellent $R^2 = 1$. Analytical limits were 0.075 µg/mL for detection and 0.229 µg/mL for quantitation, respectively. This newly developed approach exhibited high accuracy and reproducibility with RSD less than 2. Five different stress conditions were applied to assess topiroxostat stability. Forced degradation studies revealed significant degradation upon exposure to alkaline stress (12.33%), photolytic stress (14.44%), and oxidative stress (30.30%) but little degradation was observed in remaining applied stress conditions. Thus, the developed stability-indicating approach can be used for the estimation of topiroxostat in API and pharmaceutical formulations.

Introduction

Topiroxostat (TPS) is non-purine, selective inhibitor of xanthine oxidase, formerly known as FYX-051 that primarily sanctioned in Japan.[1] Its chemical composition is $C_{13}H_8N_6$, and a molar mass of 248.24 grams per mole. The IUPAC name is 4-[5-(4-pyridinyl)-1H-1, 2, 4-triazol-3-yl]-2-pyridine carbonitrile.[2] TPS is available in the form of white crystalline powder. It is soluble in dimethyl sulphoxide, (DMSO) and acetonitrile (ACN), but not in water and ethanol. The structure is shown in Fig. 1. TPS inhibits the XOR enzyme, which serves as a catalytic enzyme for the production of uric acid via the oxidative hydroxylation reaction.[3] TPS is proved a safe and effective treatment option for the management of hyperuricemia and gout.[4-7] Cardiac safety and renal protection are other advantages of this drug.[8,9]

The US FDA guidelines define stability-indicating assay methods as validated analytical procedures used to assess the shelf life of drug substances. Additionally, it is a technique that can quantify changes in drug substance concentration, unaffected by the presence of contaminants associated to the procedure, excipients, or degradation products.[10] Stability studies become very significant in determining the nature of the drug substance across time when subjected to controlled ecological variables. These investigations yield essential data for establishing optimal storage conditions, determining appropriate reanalysis intervals, and defining the shelf life of pharmaceutical drugs. Stress testing, also known as forced degradation is employed to generate samples for developing stability-indicating analytical methods but main obstacle in this designing is obtaining sufficiently degraded samples. In ideal situation involves real-time stability samples that

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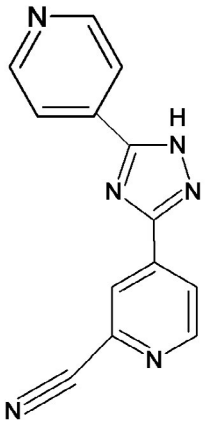

Fig. 1: Chemical structure of TPS

contain all relevant degradation products, including those that emerge under normal storage conditions. [11] High-performance liquid chromatography is a commonly utilized sophisticated analytical instrument for evaluating stability. [12] The International Council for Harmonization accurately states that "The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose. This approach is useful in new pharmaceutical development, as the regulatory agencies now mandate the submission of comprehensive validation information. The standards set forth by ICH and USP offers specific frameworks for validating analytical techniques.[13,14]

After going through the literature, it was found that only a few reported methods exist for estimating TPS, including X. Feng *et al*. 2020[15] estimated the TPS concentration in human plasma using HPLC/MS/MS, P. Suthar *et al*. 2023[16] and Paul RM *et al*. 2023[17] reported the UV spectrophotometric method, Pallavi *et al*. 2023[18] reported the RP- HPLC and spectrophotometric method; Kuranjekar YM *et al*. 2024[19] also reported RP-HPLC method, but they have not mentioned the assay procedure of said drug, as well as LoD and LoQ values which are quite found high. Gajera *et al*. 2023[20] reported the assessment of stability using HPLC method; however, detailed procedure of forced testing did not provide in this paper. Madhavi A *et al*. 2024[21] have reported RP-HPLC method development along with greenness analysis. DDLD (BEIGINJ) Pharmaceutical Technology Co. Ltd. China[22] is reported to have a patent for the method of analyzing topiroxostat–related substances. Nevertheless, these techniques lack the sensitivity when measuring TPS in small amounts. Consequently, we have opted for a DAD coupled HPLC approach which provides high sensitivity and selectivity, and is accessible on limited budgets in research labs. Taking this fact into account, a new and sensitive stability-indicating HPLC method was developed and validate for the quantification of TPS.

Materials And Methods

Materials

The pure TPS API procured from Aadhar Life Sciences Pvt. Ltd., Chincholi. TPS tablets (20 mg) were purchased from a local market under the commercially available brand name 'TOPIROXO 20' manufactured by Alkem Laboratories. Acetonitrile (LC grade) was brought from Thermo Fisher Scientific Ltd, India. Potassium dihydrogen phosphate (KH_2PO_4), ortho-phosphoric acid (OPA-AR grade), sodium hydroxide (NaOH), hydrogen peroxide (H_2O_2) and, hydrochloric acid (HCl) was brought from SD Fine Chemicals Ltd, Mumbai. For the filtration of sample solution and mobile phase, 0.45-µ nylon filters paper used.

Instruments

Using an Agilent Zorbax bonus RP C18 column, TPS was separated and estimated by using HPLC–Agilent (Infinity II 1260 model) equipped with a DAD detector. The Open Lab EZChrome software was used to monitor and integrate detector response signals. Digital analytical balance-Mettlertoledo (Model- MT 204T) was used for weighing the standards and samples and pH meter of Lab India was used for the measurement of pH.

Preparation of Solutions

Preparation of 50 mM KH_2PO_4

KH_2PO_4 (6.8 gm) was weighed accurately and added in the 1000 mL water (LC grade). After completely dissolved in water, sonication was done for 10 minutes. Ortho-phosphoric acid was added to bring the pH down to 3.3. Filtration was carried out.

Standard solution preparation

Accurate weight of TPS standard (20 mg) is added into 100 mL of diluent (50% buffer: 50% ACN). Sonication was done for 10 minutes. A working standard solution of 20 µg/mL was prepared by appropriately diluting the standard solution; validation parameters were tested using these working solutions.

Preparation of sample solution

After weighing and calculating the average weight of twenty tablets of 'TOPIROXO 20'; a mortar and pestle was used to crush the tablets into a fine powder, and an aliquot equivalent to the labeled concentration of TPS was added 100 mL (diluent); this 200 µg/mL solution was sonicated for 10 minutes using an ultra- sonication bath. After filtration, the solution was further diluted to reach a final concentration of 20 µg/mL.

Wavelength Selection

10 µg/mL solution was used for scanning in the range of 400 to 200 nm (Fig. 2).

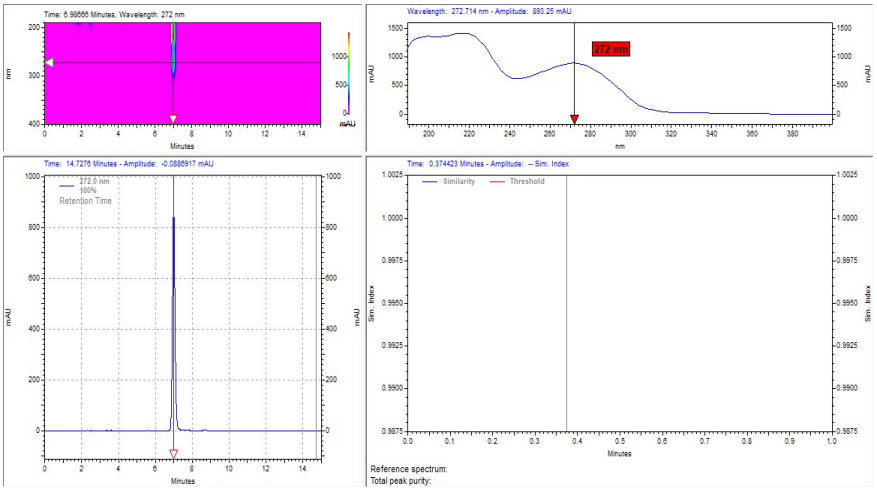

Fig. 2: Selection of the wavelength for HPLC method

Method Development

The HPLC method development for TPS involved optimizing various parameters like mobile phase composition, stationary phase selection, flow rate, column temperature, and wavelength which were systematically adjusted to achieve a desirable chromatographic separation, while some parameters remained constant, i.e., detector, injection volume, and isocratic mode. System suitability parameters were to be checked for optimization of chromatographic conditions.

Validation Procedure for Developed Method

System suitability parameters

A 20 µg/mL solution was injected in six replicates run into the HPLC system and examined with an emphasis on asymmetry, retention time, and theoretical plates, and their relative standard deviations was calculated.

Specificity and selectivity

The assessment involved injecting a blank, standard, and sample solution to examine for excipients and analyte interference

Linearity

Linearity was assessed by plotting and analyzing the regression of the peak area versus TPS concentration (0.01–120 µg/mL, prepared from the standard stock solution).

Precision

Six replicas of the TPS standard solution (20 µg/mL) were tested using the same equipment in the same laboratory for the determination repeatability of the proposed technique, and %RSD was computed. Intermediate precision was verified at various times throughout each day and on three subsequent days in succession. The %RSD was calculated for all precision studies.

LoD and LoQ

The Y-intercept (standard deviation: SD) and mean slope (S) values are replaced in the following equation: LOD = 3.3 X S.D. /S and LoQ= 10 X S.D. /S.

Accuracy or recovery

The accuracy was determined using the standard addition method. The API was spiked at 80, 100 and 120% of the label claim. The TPS standard (16,20,24 µg/mL) concentrations were spiked into tablet solution, with each measurement performed in triplicate.

Robustness

Optimal chromatographic conditions were deliberately modified to test the robustness of the method; a ± 2% adjustment was made in mobile phase ratio and column temperature. Robustness assessment was done three times by using a concentration of 20 µg/mL.

Solution Stability

Test and control sample solution stability assessments were conducted to ensure their integrity throughout the analysis. The prepared working standard solution was analyzed at various intervals (days 0, 1,and 2), and stability was assessed by examining the variation in peak area between the test and control samples.

Assay

The collective weight of 20 tablets was computed to determine their average mass. A powder sample corresponding to 20 mg of TPS concentration was added into a 100 mL volumetric flask, which already contained 50 mL of diluent. To facilitate the complete dissolution, the flask was subjected to sonication. The solution was then diluted to the 100 mL mark using the same solvent, achieving a concentration of 200 µg/mL. This solution underwent filtration through a nylon membrane. Subsequently, a 1-mL aliquot of the filtered solution was

further diluted to make a 20 µg/mL. The resulting sample was then injected into the HPLC system for the peak area measurement.

Procedure

%Assay=AT/AS × WS/DS × DT/WT × Average weight/ Label claim ×P/100 ×100[23]
Where,
AT= Test solution area
AS= Standard solution area
WS= Standard weight
DS= Standard dilution
DT= Test dilution
WT= Test weight
P= Percentage purity of standard

Stress Studies

Different stress conditions were applied to TPS samples during the forced degradation study. For acidic degradation and basic degradation, the sample was treated with 1-mL of 0.1 N HCl and 1-mL of 0.1 N NaOH at, respectively. Oxidative degradation solution was performed using 1-mL of 3% H_2O_2. Each of these conditions was maintained for 20 minutes at 70°C. Thermal degradation occurred at 80°C for 5 hours. UV degradation was conducted by exposure of API to light at 254 nm for 5 hours. To minimizes the impact of light, all of these degradation conditions were performed in the dark. All the degraded drug solutions were collected and diluted to the appropriate concentration before analysis. The standard untreated drug was compared to the assay of stressed samples.

Result And Discussion

Method Development and Optimization

A reliable stability-indicating RP-HPLC method was developed and validated for the determination of TPS. Development trials were conducted in accordance with the literature review, and the physiochemical properties of the drug were also considered. ACN was chosen as the appropriate solvent for preparing stock solutions of TPS, because TPS is freely soluble in ACN. C_8 and C18 column both was evaluated for the separation, but C18 was found to be best because it showed good resolution, optimal plate number, and tailing factor. Among the tested mobile phases, an Agilent Zorbax Bonus RP C18 analytical column was used to separate TPS with good peak symmetry in the mobile phase; 50 mM potassium dihydrogen phosphate (pH 3.3 set with OPA): ACN (20:80 v/v) produced the best result. This mobile phase provided symmetrical peak, excellent resolution, and appropriate retention time for TPS. The chromatogram of Blank, Pure TPS, and TPS tablet (20 µg/mL) is shown in (Fig. 3a, 3b, and 3c)
Optimized chromatographic conditions for TPS is given in Table 1.

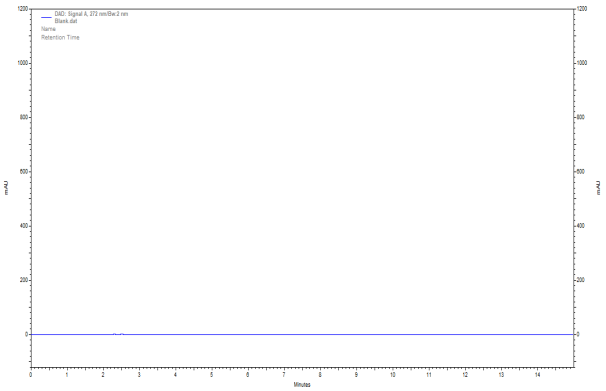

Fig. 3a: Blank chromatogram

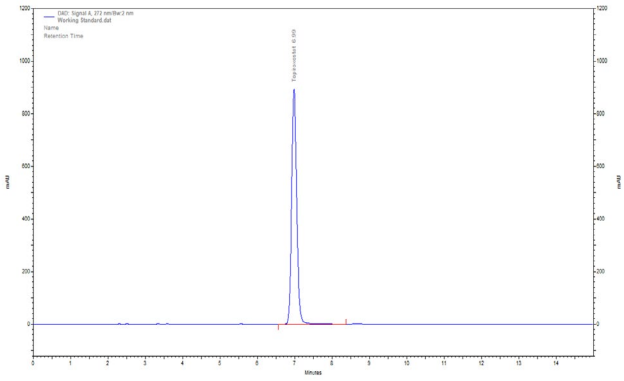

Fig. 3b: Chromatograms of pure TPS

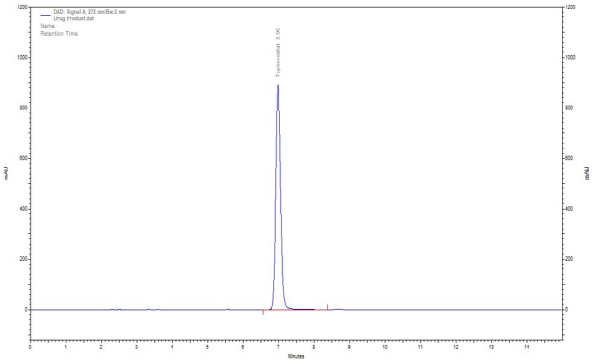

Fig. 3c: Chromatogram of TPS Tablet

Method Validation

System suitability test

The system suitability parameter indicates a very high degree of reproducibility of the developed chromatographic method. This novel method, at 20 µg/mL concentration, has shown an average retention time (Rt) of 6.99 minutes, a mean theoretical plate of 12899, and a tailing factor of 1.133, which reflects high column efficiency, good precision, and better reproducibility. These findings are detailed in Table 2.

Specificity and selectivity

The method's effectiveness in terms of specificity and selectivity was demonstrated by its ability to detect TPS

Table 1: Optimized chromatographic conditions

Chromatographic parameter	*Optimized condition*
Column	Agilent Zorbax Bonus RP C18 (250 x 4.6 mm, 5 µm).
Mobile phase	50mM/L Dihydrogen Potassium Phosphate (pH 3.3 set with ortho-phosphoric acid): Acetonitrile (20:80%v/v)
Flow rate	1.0 mL/min
Wavelength	272 nm
Column temperature	30°C
Injection volume	20 µL
Retention time	6.99 min.

Table 2: Validation parameters result

Parameter	*HPLC assay*
Linearity range	0.01–120 µg/mL
Correlation coefficient	1.0000
Retention time	6.99 Min (NLT 2.5-NMT 10 min)
Theoretical plate	12899 (More than 2000)
Tailing factor	1.133 (Less than 2)
Peak purity	1 (equal to 1)
Limit of detection (LoD)	0.075 µg/mL
Limit of quantification (LoQ)	0.229 µg/mL
Precision (%RSD)	
Intermediate precision	0.18
Repeatability	0.38
%Accuracy (n = 3)	100.01–100.90
Robustness	Robust

in the sample without any interfering factors. A positive result was observed in the chromatogram of the TPS standard, while the blank sample, which contained only the diluent, showed neither response nor interference. The chromatograms resulting from blank,standard ,and sample injections are presented in Fig. 3 (a,b, and c)

Linearity and range

Over the concentration range of0.01-120 µg/mL, the technique was linear with R^2 = 1.0000. This good linear relationship is observed, as illustrated in Fig. 4.

Precision

According to ICH requirements, the developed HPLC technique was assessed for precision and repeatability; both parameters were measured by six replicates of 20 µg/mL of drug. The established technique was found

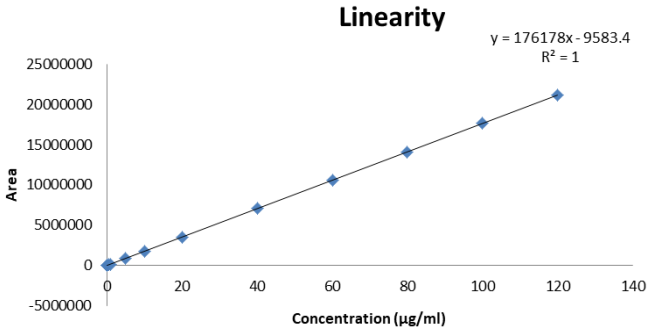

Fig. 4: Calibration curve for linearity of TPS with peak area

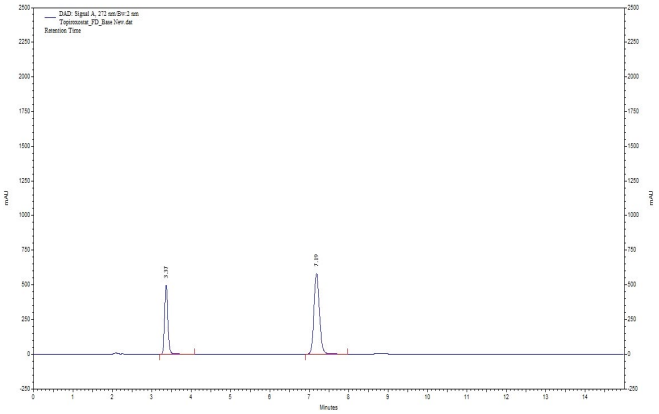

Fig. 5: Basic degradation in which TPS underwent degradation in the presence of 0.1N NaOH at 80°C, showing an additional peak at 3.37 minutes

to be precise. Table 2 confirms these findings as the percentages was less than 2.

LoQ and LoD

S/N ratios of 3 and 10 were used to check the LOD and LOQ for TPS determination. Results are summarized in Table 2, indicating enhanced sensitivity for detection and quantification.

Accuracy or recovery

This developed method confirmed that the excipients used in the formulation had no interference with TPS recovery, since the mean %recovery was 100.35 with %RSD of 0.18. The outcomes are tabulated in Table 3.

Robustness

Three samples of TPS were examined under specific conditions, including ± 2% change in mobile phase composition and ± 2% fluctuation in column temperature, focusing on how these changes affected the system suitability parameters. The calculated as % RSD was within the ICH limit, thus indicating that the method was sufficiently robust, as shown in Table 4.

Table 3: Accuracy studies results (n = 3)

Label claim (µg/mL)	*Amount added (µg/mL)*	*Amount found Mean ±SD (n = 3)*	*%Recovery*	*%RSD*
20	16	36.32 ± 0.96	100.9074	0.95
20	20	40.01 ± 0.13	100.0167	0.14
20	24	44.06 ± 0.54	100.15	0.54
Mean			100.358	0.543333

Table 4: Robustness study

Parameters		*Area (%RSD)*	*Retention time*	*Theoretical plate*	*Tailing factor*
Column oven temperature	(32°C)	0.42	6.94	12607	1.11
	(28°C)	0.09	7	12686	1.09
Increase mobile phase	(62:38v/v)	0.36	7.05	13354	1.05
Decrease mobile phase	(58:42v/v)	0.83	6.78	11247	1.13

Table 5: Forced degradation study

Stress condition	*Exposure time*	*Temperature (°C)*	*Degradant peak*	*Rt min*	*%Degradation*
0.1. N. HCl	20 minutes	70	-	-	1.94
0.1N NaOH	20 minutes	70	1	3.37 minutes	12.33
H_2O_2(3%)	20 minutes	70	-	-	30.30
Thermal	for 5 hours	80	-	-	No degradation
Light	for 5 hours	UV lamp at 254 nm	-	-	14.44

Solution stability

At room temperature, the standard solution peak area was examined every 24, 48, and 72 hours. The peak area assessed after 72 hrs. at ambient temperature, showed absolutely no changes, suggesting that the standard solution remained stable.

Assay

As a result of averaging six determinations, the mean % assay for TPS was found to be 99.36. According to the data, the %RSD of the drug fell within acceptable limits, indicating that excipients did not interfere.

Stress Studies of TPS

TPS standard solution was subjected to acidic, alkaline, oxidative, and photodegradation conditions. The TPS showed approximately 1.94% degradation under acidic condition. Under alkaline degradation, the TPS experienced nearly 12.33% degradation with a degradant peak noted (as shown in Fig. 5). The TPS exhibited 30% degradation in oxidative degradation. In the case of photolytic condition, TPS showed 14.44% degradation. TPS was remaining stable under thermal condition. The forced degradation study results are listed in Table 5.

Conclusion

In this research presents a stability-indicating approach for TPS quantitation that is characterized by robustness, linearity, precision, accuracy and sensitivity. The approach demonstrates suitable regression value, and % RSD for measuring both TPS active pharmaceutical ingredient and its commercial formulation. The results of forced degradation revealed that the drug was susceptible to basic, oxidative, and photolytic stress, but remained stable under acidic and thermal stress. Consequently, the proposed and proven stability-indicating procedure can be employed for routine TPS analysis in the laboratory.

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